CLAIMS

What is claimed is:

1. An immunotherapeutic composition, comprising activated, isolated antigen presenting cells (APCs), wherein said APCs are obtained from a patient diagnosed with a cancer having a moderate to well differentiated cancer grade and wherein said APCs are stimulated by exposure *ex vivo* to a tumor-associated antigen (TAA).

2. The immunotherapeutic composition of claim 1 wherein said tumor-associated antigen (TAA) is a tumor-specific antigen.

3. The immunotherapeutic composition of claim 1 wherein said tumor-associated antigen (TAA) is a component of a protein conjugate comprising an N-terminal moiety and a C-terminal moiety.

4. The immunotherapeutic composition of claim 1 wherein said APCs are dendritic cells (DCs).

5. The immunotherapeutic composition of claim 1 wherein said cancer is selected from the group consisting of soft tissue sarcomas, lymphomas, and cancers of the brain, esophagus, uterine cervix, bone, lung, endometrium, bladder, breast, larynx, colon/rectum, stomach, ovary, pancreas, adrenal gland and prostate.

6. The immunotherapeutic composition of claim 1 wherein said cancer is prostate cancer.

7. The immunotherapeutic composition of claim 6 wherein said cancer grade corresponds to a Gleason score of ≤ 7.

8. The immunotherapeutic composition of claim 7 wherein said patient is not refractory to hormone ablation therapy.

9. The immunotherapeutic composition of claim 3 wherein said N-terminal moiety is an APC binding protein and said C-terminal moiety is a tumor-associated antigen (TAA).

10. The immunotherapeutic composition of claim 3 wherein said C-terminal moiety is an APC binding protein and said N-terminal moiety is a tumor-associated antigen (TAA).

11. The immunotherapeutic composition of claim 3 wherein said protein conjugate is a fusion protein.

12. The immunotherapeutic c omposition of claim 11 wherein said fusion protein further comprises, between said N-terminal moiety and said C-terminal moiety, a linker peptide.

13. The immunotherapeutic composition of claim 6 wherein said N-terminal moiety or said C-terminal moiety comprises a sequence having at least 70% sequence identity with the sequence depicted in SEQ ID NO: 1 (huPAP).

14. The immunotherapeutic composition of claim 6 wherein said N-terminal moiety or said C-terminal moiety comprises a sequence having at least 80% sequence identity with the sequence depicted in SEQ ID NO: 1 (huPAP).

15. The immunotherapeutic composition of claim 6 wherein said N-terminal moiety or said C-terminal moiety comprises a sequence having at least 90% sequence identity with the sequence depicted in SEQ ID NO: 1 (huPAP).

16. The immunotherapeutic composition of claim 6 wherein said N-terminal moiety or said C-terminal moiety comprises the sequence depicted in SEQ ID NO: 1 (huPAP).

17. The immunotherapeutic composition of any one of claims 3 through 16 wherein said C-terminal moiety or said N-terminal moiety is at least 70% identical to the sequence depicted in SEQ ID NO: 3 (huGM-CSF).

18. The immunotherapeutic composition of any one of claims 3 through 16 wherein said C-terminal moiety or said N-terminal moiety is at least 80% identical to the sequence depicted in SEQ ID NO: 3 (huGM-CSF).

19. The immunotherapeutic composition of any one of claims 3 through 16 wherein said C-terminal moiety or said N-terminal moiety is at least 90% identical to the sequence depicted in SEQ ID NO: 3 (huGM-CSF).

20. The immunotherapeutic composition of any one of claims 3 through 16 wherein said C-terminal moiety or said N-terminal moiety is the sequence depicted in SEQ ID NO: 3 (huGM-CSF).

21. A method of treating a cancer patient with an immunotherapeutic composition said patient having a cancer with moderately to well-differentiated cancer cells, said method comprising the steps of:

(a) determining in said patient the differentiation state of said cancer cells wherein the presence of moderately to well-differentiated cancer cells indicates a patient susceptible to treatment with an immunotherapeutic composition; and

(b) administering to said patient a therapeutically effective dose of an immunogenic composition, wherein a reduction of 10% indicates an effective treatment of said cancer.

22. The method of claim 21 wherein said immunotherapeutic composition is the immunotherapeutic composition of any one of claims 1-18.

23. A method of inhibiting growth of a cancer cell in a patient having a moderate to well differentiated cancer grade, said method comprising the steps of:

(a) determining in said patient the grade of said cancer cell wherein a moderate to well differentiated cancer grade indicates a patient susceptible to treatment;

(b) isolating antigen presenting cells (APCs) from a patient having a moderate to well differentiated cancer grade;

(c) stimulating said APCs by exposure *ex vivo* to an immunotherapeutic composition comprising a protein conjugate comprising an N-terminal moiety and a C-terminal moiety, wherein said APCs are effective to activate T-cells to produce a cytotoxic cellular response against either said N-terminal moiety or said C-terminal moiety and wherein

the level of said T-cell activation is higher than that produced by said APCs when exposed exclusively to said N-terminal moiety or to said C-terminal moiety; and

(d) administering to said patient a therapeutically effective dose of said stimulated APCs, wherein a reduction of 10% indicates an effective treatment of said cancer.

24. The method of claim 23 wherein said cancer is selected from the group consisting of soft tissue sarcomas, lymphomas, and cancers of the brain, esophagus, uterine cervix, bone, lung, endometrium, bladder, breast, larynx, colon/rectum, stomach, ovary, pancreas, adrenal gland and prostate.

25. The method of claim 24 wherein said cancer is prostate cancer.

26. The method of claim 25 wherein said cancer grade is determined by Gleason score and wherein said Gleason score is ≤ 7.

27. The method of claim 23 wherein said immunotherapeutic composition is the immunotherapeutic composition of any one of claims 3-18.

28. A method of assessing in a cancer patient the susceptibility of the cancer to an immunotherapeutic composition, said method comprising the steps of:

(a) isolating from said patient a sample containing said cancer cell; and

(b) determining the differentiation state of said cancer cell;

wherein a moderate to well differentiated cancer grade indicates that said cancer cell is susceptible to treatment with an immunotherapeutic composition.

29. The method of claim 28 wherein said cancer is selected from the group consisting of soft tissue sarcomas, lymphomas, and cancers of the brain, esophagus, uterine cervix, bone, lung, endometrium, bladder, breast, larynx, colon/rectum, stomach, ovary, pancreas, adrenal gland and prostate.

30. The method of claim 28 wherein said immunotherapeutic composition is an immunotherapeutic composition of any one of claims 1-20.